UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,978	01/22/2004	David Hung	12.024011	5996

38732 7590 08/24/2009

CYTYC CORPORATION
Darry Pattinson, Sr. IP Paralegal
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752

EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
08/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID HUNG, PHILLIP M. OLSEN,
and DANIEL KURZ

Appeal 2009-003254
Application 10/762,978
Technology Center 3700

Decided: August 24, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 90-100, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method for lavaging a human breast duct. Claim 90 is illustrative:

90. A method for lavaging a human breast duct, said method comprising: inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network; said catheter comprising a proximal end and a distal end, and an internal lumen extending between said proximal and distal ends, said distal end including an opening for delivering lavage fluid within said duct and receiving fluid from within the duct; and a manifold hub in fluid communication with said catheter, said manifold hub comprising a distal end having a first port for infusing fluids into said hub and a second port for collecting fluid from within said hub; infusing a lavage fluid through said first port and into said hub; infusing lavage fluid from said hub into the duct or ductal network through said internal lumen of said catheter; withdrawing the lavage fluid and substances borne by the lavage fluid from the duct or ductal network through the same said lumen of said catheter and into said hub; and delivering said lavage fluid into a collection device through said second port of said hub.

The Examiner relies on the following evidence:

Cecchi US 5,843,023 Dec. 1, 1998

Hou et al., *A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge*, 195(2) Radiology 568-569 (1995).

The rejection presented by the Examiner is as follows:

Claims 90-100 stand rejected under 35 U.S.C § 103(a) as unpatentable over the combination of Cecchi and Hou.[1]

We affirm.

ISSUE

Have Appellants established error in the Examiner's prima facie case of obviousness?

---

[1] The Examiner withdrew the rejection of claims 90-100 "on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-65 and 68 of U.S. Patent No. 6,689,070 B2" from our review.

FINDINGS OF FACT

FF 1. For clarity, we reproduce Cecchi's figure 1 below:

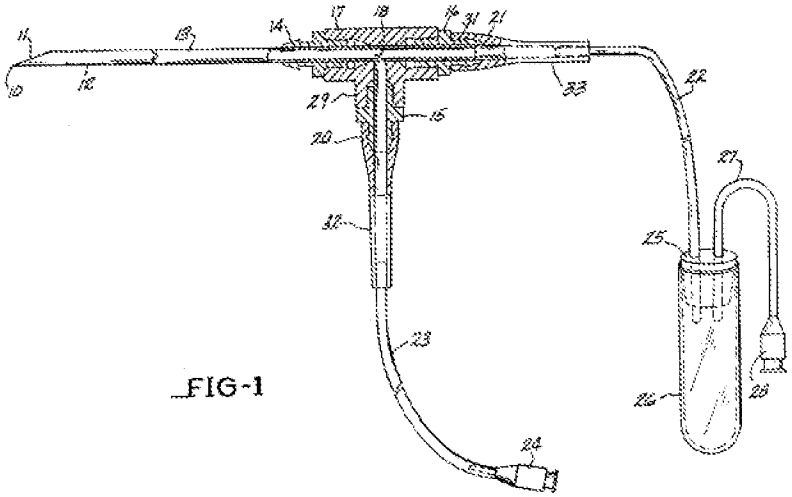

FIG-1

Cecchi's "FIG. 1 is a perspective view of a preferred embodiment of the invention" (Cecchi, col. 4, ll. 20-21).

FF 2. Cecchi teaches an apparatus, wherein a manifold hub (17) is in fluid communication with a cannula (13) (Ans. 3).

FF 3. Cecchi's manifold hub (17) comprises a "distal end having a first port (29) for infusing fluids into the hub (17) and a second port (16) for collecting fluid from within the hub (17)" (Ans. 3).

FF 4. The Examiner finds that Cecchi:

> fail[s] to disclose inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct.

(Ans. 4.)

FF 5. The Examiner finds that Hou teaches:

> a method and means for placing a lavage fluid within a breast duct and receiving fluid from within the duct, and further disclose[s] inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; and the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct.

(Ans. 4-5.)

PRINCIPLES OF LAW

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992). On appeal to this Board, Appellants must show that the Examiner has not sustained the required burden. *See Ex parte Yamaguchi*, 88 USPQ2d 1606, 1608 and 1614 (BPAI 2008) (precedential); *Ex parte Fu*, 89 USPQ2d 1115, 1118 and 1123 (BPAI 2008) (precedential)

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418.

ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 90 is representative.

Appellants contend that "[e]lement (17) in Cecchi is not a manifold hub" (App. Br. 7). Instead, Appellants contend that Cecchi's "element (17) is a 'T-connector'" (App. Br. 7). Appellants contend that "[a] manifold hub generally comprises a space with a plurality of inlets or inlet ports and a single outlet . . . [and] inherently suggests a space where fluids can be collected of [sic; or?] mixed" (*id.*). Appellants contend that "[t]he device described in Cecchi contains merely one inlet and one outlet and no area or space for the collection of fluid" (*id.*). We are not persuaded.

Appellants provide no evidence to support their contentions regarding what a manifold hub generally comprises or inherently suggests. In this regard, we note that claim 90 does not require the "manifold hub" itself to have a space where fluids can be collected and mixed. To the contrary, claim 90 defines the term "manifold hub" as "comprising a distal end having a first port for infusing fluids into said hub and a second port for collecting fluid from within said hub" (Claim 90). Cecchi's element (17) meets the requirements of Appellants' "manifold hub" (FF 1-3).

Appellants contend that because Cecchi teaches other components of the apparatus are placed between element (13) and element (17); "[e]lement (17) of Cecchi has no physical connection with the fluid which passes through the lumen of catheter (13) and thus cannot be in fluid communication with catheter (13)" (App. Br. 7). We are not persuaded.

As the Examiner explains, during aspiration, for example, fluid travels through element (13), then through element (17), and "ultimately into vial

(26)" (Ans. 7; FF 1-3). The Examiner's explanation is consistent with the structure as described in Cecchi (Fig. 2; col. 4, ll. 36-49). Therefore, despite Appellants' contentions to the contrary, Cecchi's element (13) is in "fluid communication" with element (17). While Appellants contend that "[f]luid merely passes through catheter (13) and into the collection vial (26)" (App. Br. 8); Appellants' fail to appreciate that Cecchi's element (17) is interposed between Cecchi's elements (13) and (26) (FF 1-3).

While we agree with Appellants' contention that "Hou does not teach or suggest a catheter comprising a manifold hub" (App. Br. 8); the rejection presented for our review is based on the combination of Cecchi and Hou. Cecchi teaches a manifold hub as required by claim 90.

We are not persuaded by Appellants' contention that "neither Cecchi nor Hou et al. teach or suggest a method for the collection of breast duct cells" (App. Br. 8). As the Examiner explains:

> One of ordinary skill in the art would have been able to modify the means of Cecchi to include the use of a catheter distal tip for inserting the device into the breast duct of a patient, as taught by Hou et al. . . . [S]ince the catheter is used for applying a fluid to the breast duct; the lumen of such a catheter can be used for either irrigating or aspirating or both irrigating and aspirating.

(Ans. 8.) For the foregoing reasons, we are not persuaded by Appellants' contention that there is no suggestion to combine Cecchi and Hou in the manner required by claim 90 (App. Br. 8-13).

CONCLUSION OF LAW

Appellants have failed to establish error in the Examiner's prima facie case of obviousness.

The rejection of claim 90 under 35 U.S.C § 103(a) as unpatentable over the combination of Cecchi and Hou is affirmed. Claims 91-100 fall together with claim 90.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

CYTYC CORPORATION
DARRY PATTINSON, SR. IP PARALEGAL
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752